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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/068,314      | 02/06/2002  | Michael T. Trese     | TMT-10902/04        | 8834             |

7590 01/28/2004

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| EXAMINER |
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DESANTO, MATTHEW F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3763

DATE MAILED: 01/28/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/068,314

Applicant(s)

TRESE ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-21 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-21 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 101***

1. The 101 Rejection has been withdrawn because it was improper.

***Claim Rejections - 35 USC § 102 and/or 35 USC § 103***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 7-10, and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gandorfer et al. (Ophthalmol 2001; 85:6-10).

Gandorfer et al. discloses a process for vitreous liquefaction comprising the steps of delivering a plasmin into a vitreous body and then incubating the plasmin composition in the vitreous body. (Table 1, and entire reference)

As to claims 2-4, wherein the delivery is by injection, infusion and intraocular device.  
(Methods section, page 1 and 2)

5. Claims 1-10, 13-21, 24-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Trese et al. (American Academy of Ophthalmology, ISSN 01610-6420).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye, and further delivering a plasmin inhibitor, wherein the dose of plasmin is between 0.1 and 1.0 units of plasmin. (Entire reference)

6. Claims 1-10, 13-21, 24-28 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shi et al. (Graefe's Arch Clin Exp Ophthalmol, (2002) 240:56-62).

Shi et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye, and further delivering a plasmin inhibitor, wherein the dose of plasmin is between 0.1 and 1.0 units of plasmin. (Entire reference)

***Response to Amendment***

7. The declaration under 37 CFR 1.132 filed on 11/10/03 is insufficient to overcome the rejection of claims 1-21, and 24 based upon Trese et al. as set forth in the last Office action because: the examiner still believes the product that is claimed is the same. There is no special language in the claim that links the specific plasmin of the declaration with the plasmin that is claimed. The examiner would like to point out this since this is a claim (wherein a plasmin is injected into the eye at a specific dose) this is taught by the prior art by itself or in combination with another reference. The examiner understands that the plasmins are different but there is no

language in the claim that differentiates the two plasmins, the only language is in the declaration and needs to be incorporated into the claim.

8. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Shi et al. reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). With regards to establishing a conception of the invention before the Shi et al. reference, there must be evidence showing the date, such as **a page from a lab book**, and the examiner cannot find this document that was sent early and would appreciate a copy to determine the status of the declaration with regards to establishing a conception date.

#### ***Response to Arguments***

9. Applicant's arguments filed on 11/10/03 have been fully considered but they are not persuasive.

10. The examiner still keeps the rejections because the applicant is trying to get a patent on the method of liquefying the eye with a plasmin. This is taught in the prior art references. The references also teach varying the doses through routine and well-known experimentation procedures to see whether vitreous liquefaction of the eye will occur. The examiner determines that it would be obvious to vary the concentration and volume of a dose in an experiment, especially when performing research so that a conclusion can be reached with regards to the dose

and concentration. Thus the examiner determines that normal experimentation with the prior art would make it obvious to have the concentration as claimed.

11. Even though the Declaration discusses the plasmin and how the plasmin is different with regards to the products formed and the molar concentration of the products. The examiner must take the broad definition of plasmin and not the special definition given in the Declaration, since there is no evidence of the special definition in the specification and/or claim.

12. The examiner suggests that since the plasmin allows a smaller concentration and/or dose and still effectively causes vitreous liquefaction of the eye; the applicant would want to pursue a patent on the plasmin and/or the method of making the plasmin, which is the most patentability subject matter, not the dose size and method of injecting the plasmin which is well known and well documented.

13. The examiner cites case law to further support his rejection based on the interpretations of optimization of ranges.

14. With regards to the optimization of ranges, the examiner would like to point out, that optimization within prior art conditions or through routine experimentation, generally, with differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), as well as a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable

might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

***Conclusion***

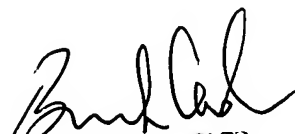
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 1-703-872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
January 23, 2004



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